

March 16, 1999

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Dockets Management Branch (HFA-305)
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 02857

I understand that you are planning to issue a Memorandum of Understanding concerning pharmacies which restricts the ability of specialized mail-order pharmacies to ship a significant portion of their orders out-of-state. I object to the definition of "inordinate amount" in the pending regulation, which causes this restriction. If this regulation had been in place over the last 10 years it would have had a significant adverse effect on my health.

I have to take large amounts of DHEA daily in order to compensate for significant adrenal failure. I was using DHEA long before it became well known. When I was first using it, I could not find it at all in local pharmacies, even though I was then living near Philadelphia. I did manage to find it by phoning the various out-of-state compounding pharmacies.

Recently, because of a change in insurance, I tried hard to find local supplies of DHEA in the strength I need. When I went to my local compounding pharmacy with my prescription, the pharmacist told me that I would have to get it from one of the large specialist compounding pharmacies, because the small ones carry a limited number of strengths, types, etc. from which to compound. My health insurance company (ValueRx) has a mail order compounding pharmacy which it encourages its customers to use for continuing prescriptions, but even this compounding pharmacy can't compound the pills I need. I can get them from Madison Pharmacy Associates, of the Women's Health Group.

How do you expect the people who need medication that is needed by too few people to be carried by ordinary pharmacies to get the medication they need? It seems likely that if the regulation proposed is enacted, some people, particularly ones in thinly populated states, could be in real serious trouble, as there just wouldn't be enough people with particular special needs for it to be economically feasible to stock medicines for those needs.

Sincerely,

Mary B. Williams

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